

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING)
PHARMACY, INC. PRODUCTS LIABILITY)
LITIGATION)
) MDL No. 13-2419
) Dkt. No 1:13-md-2419 (RWZ)
_____)
THIS DOCUMENT RELATES TO:)
)
All Cases Against the Saint Thomas)
Entities)
)
_____)

**SAINT THOMAS ENTITIES' REPLY IN FURTHER SUPPORT OF THEIR GLOBAL
MOTION FOR PARTIAL SUMMARY JUDGMENT ON CLAIMS FOR ACTUAL
AGENCY AND DIRECT LIABILITY**

The Saint Thomas Entities¹ file this Reply in further support of their *Global Motion for Partial Summary Judgment on Putative Claims for Actual Agency and Direct Liability* (Docket #2743) ("Global MSJ")² on the MDL Plaintiffs' claims against them ("Tennessee Plaintiffs"):

INTRODUCTION

The Saint Thomas Entities demonstrated there is no evidentiary basis for any of the Tennessee Plaintiffs' actual agency claims against them, nor do these Plaintiffs have any legal or factual basis for a claim of "direct liability." The PSC responds with a smattering of evidence it claims creates a fact issue. The PSC's "proof" either relate to apparent agency or the veil-piercing claims the Court has previously dismissed, or are taken entirely out of context and misinterpreted.

¹ Saint Thomas West Hospital, formerly known as St. Thomas Hospital ("Hospital"), Saint Thomas Network ("Network"), and Saint Thomas Health ("Health") (collectively, the "Saint Thomas Entities"). For consistency, the Saint Thomas Entities will continue to use the terms they defined in their Global MSJ.

² See also *Saint Thomas Entities' Memorandum in Support of Global Motion for Partial Summary Judgment on Putative Claims for Actual Agency and Direct Liability* (Docket #2744) ("Global Memo") and *Saint Thomas Entities' Statement of Undisputed, Material Facts in Support of Their Global Motion for Partial Summary Judgment on Claims for Actual Agency and Direct Liability* (Docket #2745), including all exhibits ("SMF Global MSJ").

The PSC’s theory is that “the Saint Thomas Healthcare system”³—which is not even a legal entity, but a catch-all that even the PSC does not fully define—should have stopped STOPNC from doing something that the Saint Thomas Entities knew nothing about or put policies in place that they had no reason to know were necessary. This “health system” argument is premised on piercing the corporate veil between the Saint Thomas Entities (a claim the Court previously dismissed) to create a single “system,” disregarding the board of directors at STOPNC (which had the actual legal authority to make decisions), and then asserting that a direct duty was owed by the “system” to the patients of STOPNC. Quite simply, the theory lacks any basis in law, which absent veil-piercing, treats each company separately. The PSC has offered neither precedent nor proof for its assertion that the Saint Thomas Entities owed any duty of care to any of the Tennessee Plaintiffs while they were at the STOPNC premises, receiving medical care from STOPNC staff.

As to actual agency, there is simply no proof that any of the Saint Thomas Entities—much less all three—exercised control over, or even had the right to control, STOPNC’s procurement of medication for individuals who were solely patients of STOPNC and the Howell Allen Clinic at the time. Summary judgment should be granted on both of these claims.

ARGUMENT AND AUTHORITIES

I. There Is No Legal or Factual Basis for the Direct Liability Claims

The direct liability claims should be easily adjudicated as a matter of law because the PSC cannot articulate a cognizable legal duty. “[W]ithout the establishment of a duty, there can be no negligence.” *Estes v. Peels*, No. E199900582COAR3CV, 2000 WL 1424808, at *3 (Tenn. Ct. App. Sept. 21, 2000) (citing *Doe v. Linder Constr. Co.*, 845 S.W.2d 173, 178 (Tenn. 1992)). The existence of a duty is a question of law. *Carson v. Headrick*, 900 S.W.2d 685, 690 (Tenn. 1995).

³ *Memorandum in Support of Plaintiffs’ Steering Committee’s Opposition to Saint Thomas Entities’ Global Motion for Partial Summary Judgment on Claims for Actual Agency and Direct Liability* (Docket #2818) (“Opposition”) at 16.

The PSC's Opposition does not address it, but instead argues facts concerning a purported breach.

The PSC cites nothing for its theory that the Saint Thomas Entities owed a duty to the Tennessee Plaintiffs—with whom they had no preexisting relationships at the time of their MPA injections.⁴ Instead, PSC's "duty" is defined solely by the purported breach: "By failing to communicate that important patient information across its organizational structure, Saint Thomas Health and Saint Thomas Hospital breached their duty of reasonable care." Opposition at 16. The PSC's basic theory is that Martin Kelvas' decision that his hospital pharmacy employees should not purchase from NECC due to concerns regarding legality⁵ gave rise to a duty to tell doctors and physician-run clinics—who were indisputably *not* under his authority and did not consult with him, SMF Global MSJ ¶¶ 14-18⁶—about his concern.

To illustrate why the PSC's argument cannot withstand scrutiny under the law of corporate governance, it is well established that the directors of a company owe a duty of care in making decisions solely to the company itself. *See, e.g., Sanford v. Waugh & Company*, 328 S.W.3d 836, 844 (Tenn. 2010) (explaining that "creditors may not directly sue officers and directors of a corporation because they allegedly failed to properly manage corporate affairs"). Accordingly, if the directors should have implemented a policy prohibiting purchases from compounding

⁴ As to some of the Tennessee Plaintiffs, the Hospital did have a patient relationship when it treated them *after* the meningitis outbreak, but that subsequent treatment cannot give rise to any duty to set procurement policy for STOPNC at the time of the patients' injections.

⁵ Kelvas' discussion with the Tennessee Board of Pharmacy had nothing to do with STOPNC, as physician practices and ambulatory surgery centers are not subject to its authority.

⁶ The PSC points out that Kelvas advised particular pharmacy personnel at certain affiliated hospitals not to purchase from compounding pharmacies. Opposition at 19. But Kelvas, who is a pharmacist and not a physician, had no role in instructing physicians like Dr. Culclasure who operated in clinics that did not have pharmacies. *See* Docket #2820-12 at 96:19-100:11; *see also* Exhibit 1 (attached) at 64:19-67:25. STOPNC was not on the list of the entities for which the Pharmacy Council on which Kelvas sat had any authority. Exhibit 1 at 67:23-25. General statements to the effect that STOPNC was subject to "the policies and philosophies" of the "Saint Thomas Entities," Opposition at 22, are not competent evidence to create a fact issue in the face of this specific and uncontroverted testimony from the Director of Pharmacy Services of Saint Thomas Hospital that the Hospital had no authority over STOPNC as to drug procurement.

pharmacies, that is a claim that only the company (STOPNC) owns and can assert. In other words, STOPNC's directors cannot be sued under the PSC's theory because the law is clear no such direct duty exists. And yet the PSC claims such a direct duty somehow exists by the partial owner appointing the director (or an affiliated company with one similar owner).

The only legal authority that the PSC can cite for such a broad and unprecedented duty are cases involving general concepts of negligence. Notably, the PSC fails to engage—much less distinguish—any of the statutory or judicial authority discussed in the Saint Thomas Entities' Global Memo as to the impact of Tennessee LLC Act, which independently precludes any claims against Network (owning 50% of STOPNC) or the Network-appointed board members of STOPNC (two of the four board seats). *See* Global Memo at 15-17.⁷ Nor does the PSC address the Tennessee authority demonstrating that legal duties are not lightly implied and must have some grounding in some positive authority, such as statute or contract. *See* Global Memo at 17-19. The PSC is unable to cite any statute or point to anything in the voluminous documents that define and detail the relationships between the Saint Thomas Entities and STOPNC where the parties agreed that they would play any role in setting pharmaceutical procurement policies for STOPNC.

None of the cases cited by the PSC in its “direct duty” argument supports the extension of a duty by a pharmacist or other healthcare provider to a person with whom it has no existing relationship. *See, e.g., Roe v. Catholic Diocese of Memphis, Inc.*, 950 S.W.2d 27, 31 (Tenn. Ct. App. 1996) (plaintiffs' son was enrolled in a preschool program run by the defendants); *AFG Indus., Inc. v. Holston Elec. Coop.*, 556 F. Supp. 33, 34 (E.D. Tenn. 1982) (refusal to create a duty out of whole cloth where the court was “not cited to, nor has its research disclosed, any statute, regulation or case authority imposing [one] ...”); *Dooley v. Everett*, 805 S.W.2d 380, 381-82,

⁷ Network, which is not even mentioned in the PSC's articulation of “duty,” Opposition at 16, and is never alleged to have “participated in the wrong,” should be dismissed on this independent basis.

(Tenn. Ct. App. 1990) (referencing statute and recognized common-law duties specific to pharmacists in considering question of pharmacist's duty to warn pharmacy customer about risk of harmful reactions due to the interaction of two prescriptions he filled for the same minor patient); *Staples v. CBL & Assocs.*, 15 S.W.3d 83 (Tenn. 2000) (mall owner, its security provider, and anchor store owed duty to protect a store patron from abduction ***after she advised workers at one of the stores in the mall that she was being stalked*** (emphasis added)); *Burroughs v. Magee*, 118 S.W.3d 323, 335 (Tenn. 2003) (refusing to "impos[e] a duty on a physician to consider third parties when making prescribing decisions [because it] could compromise the physician's care of individual patients").

Although the PSC cites cases applying the balancing test that the Tennessee Supreme Court uses to determine the existence of a legal duty, it does not apply the balancing test itself: "[T]raditional duty analysis entails balancing of the foreseeable gravity of the potential risk of harm against the burden imposed on the defendant to prevent the harm." *Rice v. Sabir*, 979 S.W.2d 305, 309 (Tenn. 1998). None of the cases the PSC cites or the undersigned has researched has found a legal duty under this balancing test where the defendant did not know and was not on notice of the risk—as is the case here. The PSC's position appears to be that so long as companies share some amount of ownership—even if they have separate boards and there is no basis for veil-piercing—each owes a duty of care to make sure they are all properly managed. Such a duty would be unworkable and would turn corporate governance and decades of business law on its head.

The PSC does not controvert the following facts that doom its direct liability theory:

- All of the STOPNC patients were referred directly by Howell Allen Clinic doctors. SMF Global MSJ ¶ 13. The Saint Thomas Entities had no interaction with or relationship to the Tennessee Plaintiffs at the time of their injections at STOPNC.
- STOPNC is located in a building that is not owned by the Saint Thomas Entities or any of their affiliates, and Howell Allen Clinic is the tenant on the lease. SMF Global MSJ ¶ 12. There is no evidence that the Saint Thomas Entities have any

control over the property where STOPNC administered the contaminated ESIs to the Tennessee Plaintiffs.

- The Saint Thomas Entities did not employ any of the personnel at STOPNC and did not supervise them. SMF Global MSJ ¶ 1, 11.
- None of the Saint Thomas Entities were involved in the decision of Dr. Culclasure or Nurse Schamberg to purchase MPA from NECC. SMF Global MSJ ¶ 15.⁸
- Hospital has never supplied pharmaceuticals, medical supplies, or procurement services to STOPNC. SMF Global MSJ ¶ 15.
- Dr. Culclasure did not even know who Hospital-pharmacist Kelvas was and did not consult with anyone at the Saint Thomas Entities before authorizing the purchase of MPA from NECC. SMF Global MSJ ¶¶ 17-18.
- Nurse Schamberg did not consult with anyone at the Saint Thomas Entities before authorizing the purchase of MPA from NECC. SMF Global MSJ ¶ 17.
- Neither the Network-appointed STOPNC board members nor anyone else working for the Saint Thomas Entities had any idea that STOPNC was purchasing from any compounding pharmacy, including NECC. SMF Global MSJ ¶¶ 17-18.

These undisputed facts prevent any duty from arising under Tennessee law. *See, e.g., Choate ex rel. Clayton C. v. Vanderbilt Univ.*, 2016 WL 308574, at *5 (Tenn. Ct. App. Jan. 25, 2016) (finding that Vanderbilt had no duty of care where employees of another company not under the direction of Vanderbilt were responsible for plaintiff's admission to the clinic and for weighing him prior to his dialysis treatment and Vanderbilt had no control over the area where the accident occurred or were on notice of a dangerous condition).

Notwithstanding the lack of legal precedent and factual support, the PSC points to an affidavit from its expert, James Gray, who fails to articulate a standard of care for these defendants. Opposition at 20-22. Like the PSC, its expert speaks only of the purported breach. *See* TENN. CODE ANN. § 29–26–115(a) & (b) (Standard of care, breach, and causation must each be supported

⁸ Although the PSC “dispute[s]” all of ¶ 15, its response is that the “Saint Thomas Health system was obligated to protect the safety of patients,” followed by a repetitive recitation of the “facts” that they contend reflect a breach. The PSC has no answer—much less controverting proof—as to the now uncontroverted testimony of the Saint Thomas Entities and STOPNC witnesses establishing this fact.

with expert testimony.). The Saint Thomas Entities will be filing a motion to challenge the PSC's expert at the appropriate time. For purposes of this motion, his report is incompetent to create a fact issue on duty because the existence of a duty is a legal question for the Court, *Carson*, 900 S.W.2d at 690, not a factual matter than an expert can create.⁹ And independently, Gray has failed to articulate a standard of care, and the PSC has not offered any other expert proof to support one, so has failed to satisfy one of the statutorily required elements of the Tennessee Plaintiffs' claims. Summary judgment should therefore be granted on the putative claims for direct liability.

II. The PSC Has Not Substantiated its Claim of *Actual Agency*

The principal's *right to control* the actions of the agent is "the essential test" in determining whether an agency relationship exists. *Jack Daniel Distillery v. Jackson*, 740 S.W.2d 413, 416 (Tenn. 1987). But actual control may be even more significant in the final analysis. *White v. Revco Disc. Drug Ctrs., Inc.*, 33 S.W.3d 713, 723 (Tenn. 2000) (citation omitted).

The same undisputed facts listed above in part I also defeat the Tennessee Plaintiffs' claims for actual agency.¹⁰ The PSC's lead argument in this regard is that STOPNC shared a name with the Saint Thomas Entities and was part of "the Saint Thomas Health system."¹¹ Opposition at 2. Having a similar name—especially one as common as "Saint Thomas"—is not proof of actual authority to bind separately incorporated entities. And the suggestion that "the Saint Thomas

⁹ The PSC suggests that Gray opined that the Saint Thomas Entities were "obligated to take appropriate steps to ensure that appropriately trained personnel were in place at [STOPNC] in order to protect the safety of patients with regard to the procurement of steroids for use in ESIs." *Plaintiffs' Steering Committee's Response to the Saint Thomas Entities' Statement of Undisputed, Material Facts in Support of Their Global Motion for Partial Summary Judgment on Claims for Actual Agency and Direct Liability* (Docket #2819) ("SMF Response") at 10-11. Gray's declaration says no such thing. In paragraphs 43-45 and 48, the only place where he addresses the Saint Thomas Entities, he states only that they failed to protect STOPNC's patients by failing to order STOPNC not to purchase from NECC. See Docket #2820-19 ¶¶ 43-45 & 48.

¹⁰ Contrary to the PSC's suggestion, the Saint Thomas Entities expressly preserved their challenges to the Tennessee Plaintiffs' apparent agency claims. See Global Memo at 2, 10-11 & nn.4, 7.

¹¹ There is no legal entity known as the "Saint Thomas Health system," which is a term the PSC has coined in depositions to make its point. Much like its misleading reference to STOPNC as the "Saint Thomas Clinic," this is a nickname not used by anyone else.

Entities and Saint Thomas Clinic purposefully and consistently hold themselves out to the public as a singular organization,” *id.*, has nothing to do with **actual** agency. “Public perception” of a link between STOPNC and the Saint Thomas Entities cannot create an actual delegation of authority that, according to the undisputed record, never happened. The PSC is confusing apparent agency considerations with actual agency requirements.

The PSC also attempts to create fact issues as to the undisputed facts regarding the Saint Thomas Entities’ right of control by mischaracterizing or recharacterizing the Saint Thomas Entities’ statements or its own “proof.”¹² Scott Butler’s quote to the effect that the parties had “equal control as far as the venture itself was concerned,” *e.g.*, Opposition at 5; SMF Response at 4, is inconsequential. That testimony was provided in response to a line of questions about each investor having the right to appoint two board members, nothing more. By definition, owners of company stock have the right to vote to appoint board members. Dr. Batchelor’s recognition that the Board “had ultimate responsibility for the operation of” STOPNC, Opposition at 5; SMF Response at 4, and Dr. Schatzlein’s acknowledgment of the board’s “oversight of management” function, *id.* at 7, simply states the law of corporate governance; it is not evidence that their respective employers controlled STOPNC’s operations. The idea that because an LLC, organized under the laws of Tennessee, with a board that met quarterly and recognized all corporate formalities, was “controlled” by that board such that the owners are now liable for all acts of the LLC is both unprecedented and ill-advised. The entire reason for appointing a board of directors (or governors) is to ensure proper oversight of the management a company. Indeed, a premise of the corporate shield imposed by the Tennessee LLC Act is that a company’s management will be reviewed by and report to an elected board with fiduciary duties to the company. *See* Global Memo

¹² Respecting the ten-page limit for replies in Docket #1524 at 3, the Saint Thomas Entities will not attempt to address them all.

at 15-17. The PSC's arguments here would eviscerate for all Tennessee limited liability companies the legal protections afforded to them by Tennessee law pursuant to the Tennessee LLC Act. So long as the owners of the LLC appointed a board and recognized corporate formalities (the premise for separation of corporate liability), the owners would become liable under actual agency.

Contrary to the PSC's truncated review of the documents, the undisputed record confirms that management functions were in fact delegated to Howell Allen. *See* Opposition at 5-7; SMF Global MSJ ¶ 10 Exhibit J (Docket #2745-10) (Addenda to the HAC-STOPNC Services Agreement). Under the Operating Agreement, the Board had the right to do so. *Id.* ¶¶ 9-10 & Exhibit F (Docket #2745-6). And the suggestion that § 6.10 of that Operating Agreement provided "the Saint Thomas Entities" the right to unilaterally require STOPNC "to take action or refrain from taking actions that could jeopardize the interests of the Saint Thomas Entities," Docket #2819 at 7, is a blatant misreading of the agreement. Section 6.10 provides *both* owners of STOPNC the right to prevent fundamental changes to corporate structure such as merger, selling off the LLC's assets, or amending its articles of incorporation without both parties' consent. *Id.* § 6.10. It is a standard protection in any LLC agreement, not evidence of right of control over day-to-day operations, and certainly not proof of any involvement with STOPNC's pharmacy procurement.

The PSC also tries to controvert the legal documents with testimony about general expectations and preferences. *E.g.*, Opposition at 7-8; SMF Response at 11. It is not surprising that the investors in a healthcare clinic would expect the clinic to conduct its work with concern for patient safety and according to the applicable standards of care and to contract for protection from losing their own non-profit status. This testimony is immaterial to the issue of actual control.

Further, the PSC attempts to create a fact issue as to possible grounds for piercing STOPNC's corporate veil, pointing to claimed shared control, use of letterhead and conference rooms, and the public-relations assistance the Saint Thomas Entities provided to STOPNC *after*

the outbreak. *See generally* SMF Response. The Court has already dismissed Plaintiffs’ veil-piercing claims on the pleadings, Docket #1360 at 49-50, so there is no basis for holding any of the Saint Thomas Entities liable to the Tennessee Plaintiffs based on their corporate relationships. Indeed, the “proof” the PSC points to is little more than proof of affiliation (*i.e.*, some amount of common ownership), which is wholly irrelevant to actual agency.

Finally, the suggestion that the Saint Thomas Entities’ actions in assisting STOPNC in handling media and patient relations after the outbreak, *e.g.*, Opposition at 14-15; SMF Response at 19, is somehow evidence of pre-crisis control is unsupportable. The statement of Dr. Schatzlein about “over[iding] the board structure” is taken entirely out of context. In the very next sentence of his testimony, he explains that he authorized the chief communications and marketing director to assist STOPNC in its communications with patients: “Remember now, this is after all of the harm had been done, and what we’re doing now is, again, all hands on deck to try to help these patients,” confirming that it was all “for the purpose of promoting patient health.” Docket #2820-1 at 63:16-22.¹³ The Saint Thomas Entities have a faith-based ministry, a significant part of which is helping others in need. Scott Butler testified that the clinic was overwhelmed and had no one to handle communications with so many patients at the time. *See Exhibit 2* (attached) at 90:2-91:15.¹⁴

The undisputed facts show that the Saint Thomas Entities did not have control over the STOPNC Defendants as to patient care or pharmacy procurement policy and did not attempt to exercise control (and were precluded from exercising control) over Dr. Culclasure.¹⁵

¹³ The PSC’s paraphrase of Dr. Schatzlein’s deposition that the Saint Thomas Entities were “direct[ing] STOPNC’s] operations,” Docket #2819 at 5, does not find support in his testimony, which was clearly about rendering aid in the context of patient communications, not STOPNC’s general operations.

¹⁴ The PSC also erroneously states that STOPNC was mentioned on both the Saint Thomas Entities’ websites and Howell Allen, Opposition at 13 & n.53 (citing “Ex. C, Climer Dep. 143:24-144:6”), but the citation to Rebecca Climer’s deposition says nothing about the Saint Thomas Entities’ websites—only Howell Allen. The PSC did not attach the cited pages in its exhibits. *See Exhibit 3*. There is no evidence that STOPNC was mentioned on the Saint Thomas websites prior to the meningitis outbreak.

¹⁵ The PSC recognizes the authority in this regard, but claims that it does not impact their claims against

CONCLUSION AND PRAYER

For these reasons and the ones set forth in their Global MSJ, the Saint Thomas Entities request that the Court grant the relief set forth in the Global MSJ.

Dated: May 5, 2016

SAINT THOMAS WEST HOSPITAL,
FORMERLY KNOWN AS ST. THOMAS
HOSPITAL, SAINT THOMAS
NETWORK, AND SAINT THOMAS
HEALTH

By their attorneys,
/s/ Sarah P. Kelly
Sarah P. Kelly (BBO #664267)
skelly@nutter.com
NUTTER McCLENNEN & FISH LLP
Seaport West
155 Seaport Boulevard
Boston, Massachusetts 02210
(617) 439-2000
(617) 310-9461 (FAX)

Health or Network or the apparent agency claims. Opposition at 15-16 & n.66. *Edmonds v. Chamberlain Mem. Hosp.*, 629 S.W.2d 28 (Tenn. Ct. App. 1981), predates the seminal apparent agency decision in *Boren ex rel. Boren v. Weeks*, 251 S.W.3d 426 (Tenn. 2008), but stands for the same proposition. And the Saint Thomas Entities have not moved for summary judgment against the Bellwether Plaintiffs' **apparent agency** claims on this ground. But Tennessee's prohibition against the corporate practice of medicine does impact the Tennessee Plaintiffs' actual agency claims against all the Saint Thomas Entities because it confirms what the undisputed record shows—that none of the Saint Thomas Entities exercised control over Dr. Culclasure's medical judgment regarding the procurement of pharmaceutical products used in STONPC's treatment of the Tennessee Plaintiffs. See Global Memo at 13-14.

OF COUNSEL:

Yvonne K. Puig*

Texas State Bar No. 16385400

yvonne.puig@nortonrosefulbright.com

Adam T. Schramek*

Texas State Bar No. 24033045

adam.schramek@nortonrosefulbright.com

Eric J. Hoffman*

Texas State Bar No. 24074427

eric.hoffman@nortonrosefulbright.com

NORTON ROSE FULBRIGHT US LLP

98 San Jacinto Blvd. Suite 1100

Austin, Texas 78701

(512) 536-2450

(512) 536-4598 (FAX)

Marcy Hogan Greer*

State Bar No. 08417650

mgreer@adjtlaw.com

ALEXANDER DUBOSE JEFFERSON &
TOWNSEND LLP

515 Congress Avenue, Suite 2350

Austin, Texas 78701-3562

(512) 482-9300

(512) 482-9303 (FAX)

*Appearing *Pro Hac Vice*

CERTIFICATE OF SERVICE

This certifies that a true and accurate copy of the foregoing was served on all parties of record by virtue of the Court's electronic filing system this 5th day of May, 2016.

/s/ Sarah P. Kelly

SARAH P. KELLY